



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

an

| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------------|------------------|
| 10/043,550  | 01/11/2002  | Craig Glascott       | DEP-662                       | 7299             |
| 27777   | 7590        | 09/23/2003           |                               |                  |
| AUDLEY A. CIAMPORCERO JR.<br>JOHNSON & JOHNSON<br>ONE JOHNSON & JOHNSON PLAZA<br>NEW BRUNSWICK, NJ 08933-7003 |             |                      | EXAMINER<br>MELSON, CANDICE C |                  |
|   |             |                      | ART UNIT<br>3732              | PAPER NUMBER     |
|   |             |                      | DATE MAILED: 09/23/2003       |                  |

9

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                   |                 |
|------------------------------|-------------------|-----------------|
| <b>Office Action Summary</b> | Application No.   | Applicant(s)    |
|                              | 10/043,550        | GLASCOTT, CRAIG |
|                              | Examiner          | Art Unit        |
|                              | Candice C. Melson | 3732            |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-8 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-8 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1-3, and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Tatar (USPN 5,910,142). Tatar discloses “a polyaxial pedicle screw device” which “includes a screw having a curvature head and a rod receiving body”. “Referring now to FIG. 1, a side view of the screw portion of the present invention, comprising a threaded shaft and a partially curvature head, is shown. The screw 100 comprises a threaded shaft 102” (columns 4-5, lines 66-67 & 1-2). “The curvature head 104 includes a constant radius of curvature than lower portion 106 which is convex and therefore defines a partial hemispherical section” (column 5, lines 5-7). This also anticipates Claim 5. “Referring now to FIG. 2, the body element 120 is provided in a side cross-section view. The body 120 is generally cylindrical and has an axial bore 122 extending therethrough. The body includes a channel 123” (column 5, lines 14-17). Furthermore, “the lower portion of the axial bore 122 includes a curvature taper 126 which forms a socket, preferably having the identical radius of curvature of the curvature of the lower half 106 of the screw 100. The bottom opening 128 of the axial bore 122 is larger than the shaft 102 of the screw 100, but is less than the diameter of the head 104, so that the head can be nested in the socket 126 at the bottom of the bore 122, with the undersurface 106 of the head slidably (initially) nested against the tapered interior surface” (column 5, lines 23-32). This also

Art Unit: 3732

anticipates Claim 6. With respect to Claim 2, "Referring now to FIG. 4, the set screw 140 of the present invention is provided in a side cross-section view. The set screw 140 has a cylindrical body having a threading 142 thereon" (column 5-6, lines 66-67 & 1-2). "The set screw further includes a concave underside 144" (column 6, lines 8-9). "The subsequent insertion and tightening of the set screw 140 downward onto the ferrule 130 causes the slot in the ferrule 130 to compress and lock the ferrule to the rod and the ferrule to compress against the head 104 of the screw 100" (column 6, lines 34-38). Thus, indirectly the nut compresses the convex portion of the head into the concave portion of the receiver. As to Claim 3, FIG. 2 shows the U-shaped portion of the receiver, which is for receiving an elongated member.

2) Claims 1-3, and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Biedermann et al (5,443,467). "The bone screw comprises the screw member proper with a threaded portion 2 and a head 3. The head 3 has a spherical segment shape at the side adjacent to the threaded portion" (column 2, lines 31-33). This also anticipates Claim 5. "The bone screw further comprises a cylindrical receiver member 5. The receiver member has a first axial bore 7 provided at one end thereof and having a diameter which is larger than the diameter of the threaded portion 2 and smaller than the diameter of the head 3. The receiver member 5 further comprises a coaxial second bore 8 which is open at the end of the receiver member opposite to the first bore 7 and has a diameter sized for passing the screw member through the open end, whereby the threaded portion is guided through the first bore 7 and the head 3 engages the base of the second bore" (column 2, lines 39-49). This also anticipates Claim 6. As to Claim 2, "the screw member further comprises a head locking nut 12". "The head locking nut 12 has a spherical countersunk portion 15 at its side facing the head 3" (column 2, lines 64-68). This also

Art Unit: 3732

anticipates Claim 5. With respect to Claim 3, “the receiver member 5 further comprises a U-shaped recess 6 which is symmetric with respect to the center of the member and shaped so that the base thereof points towards the first bore 7 and the two lateral legs extend to the open end opposite to the first bore” (column 2, lines 56-61). As to Claim 7, in an alternate embodiment, “a pressure disk 18 is provided in place of the head locking nut and formed to have a spherical countersunk portion 19 at its side facing the head 3. The radius of the countersunk portion 19 substantially corresponds to the radius of the spherical segment -shaped portion of the head 3” (column 3, lines 45-50). Therefore, it is inherent that there is some type of interference fit between the pressure disk and the head. The Examiner takes interference fit to mean some type of frictional fit not necessarily causing a locking fit between the pressure disk and the head.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1) Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tatar in view of Sherman et al (USPN 5,885,286). Tatar discloses the claimed invention except for the concave portion of the receiver formed of titanium. Sherman et al teach a bone screw assembly where “all of the components of the bone screw assembly, including the spinal rod, are formed of titanium” (column 3, lines 60-62). It would have been obvious to one of ordinary skill in the art

at the of the invention to incorporate the components formed of titanium as taught by Sherman et al in order to provide a material that is biocompatible and durable.

2) Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann et al. Biedermann et al disclose the invention as stated in Claim 8 except for the pedicle screw having a radius of curvature of 0.05mm. It would have been an obvious matter of design choice to make the radius of curvature of the head of the pedicle screw 0.05mm since applicant fails to show criticality of a radius of 0.05mm. In the specification, Applicant shows that there is a criticality for having an interference fit versus a non-interference fit however, throughout the testing Applicant does not vary the diameters of the head of the screws or the pressure disk.

#### *Response to Arguments*

Applicant's arguments filed 07/11/03 have been fully considered but they are not persuasive. Applicant submits that Tatar makes no express or implied indication of an interference fit between the screw and the body element. Furthermore, Applicant submits "Biedermann et al do not expressly disclose a device with an interference fit. Rather, they propose "substantial correspondence" between the radius of curvature of the screw and the receiver". Applicant further asserts "substantial correspondence" demonstrates intent to achieve identical or at least substantially close to identical, radii of curvature.

Examiner submits that the interference fit achieved in the present invention is caused "during compression" which "causes the material to deform somewhat to provide an interference fit". Tatar may not expressly indicate the interference fit however, it is inherent since Tatar discloses that "the insertion of a top set screw compresses down on the ferrule, locking the rod in

position, and onto the screw head, locking it and the body in position, thus completely securing the assembly (see abstract). Furthermore, Biedermann et al propose "substantial correspondence". The Examiner submits that the correspondence between the screw and the body does not necessarily demonstrate intent to achieve identical radii of curvature. In fact, correspondence can exist where there is similarity or analogy between parts. Correspondence merely indicates that there is some sort of compatibility between the bone screw and body. Corresponding is somewhat indefinite – *In re Slayter* (CCPA) 125 USPQ 345. Thus, the rejections to Claims 1-8 are sustained.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 3732

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Candice C. Melson whose telephone number is (703) 305-8128. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

*CCM*  
Candice C. Melson

*Cary E. O'Connor*  
Cary E. O'Connor  
Primary Examiner